Position: Clinical Research Coordinator

Department: Clinical

Reporting to: Associate Director, Clinical Strategy

Job Description:

The Clinical Research Coordinator is responsible for completing clinical activities related to MIVI Neuroscience, Inc. clinical studies and supporting the daily operations associated with those studies, ensuring clinical trials are conducted in accordance with international Regulatory and Ethical guidelines for Good Clinical Practices (GCP) and International Conference on Harmonization (ICH).

Responsibilities:

- Assist in the day-to-day management of the Trial Master File, including filing documents appropriately and ensuring files are audit-ready
- Tracking and filing appropriate training documentation
- Assisting with shipping product to the sites as needed
- Compilation of study binders for site start-up activities
- Real-time management of Clinical inventory
- Attends and participates in study meetings (i.e. Investigator Meetings, study team calls)
- Assist in the development of clinical study related documents, study documents and templates, Regulatory documents, training presentation, instructions, Investigator's Brochure, Core lab procedures, etc.
- Assist in maintenance of case report forms, worksheets and electronic data collection system(s).
- Serve as contact for clinical study sites to address study questions
- Ensure investigational sites are supplied with necessary items to perform the study: subject binders, documents, core lab supplies, study device, etc.
- Monitor clinical study safety including serious adverse events collection and notifications, interact with clinical events committee and data safety monitoring board and assist in all necessary safety reporting.
- Oversee data collection, data queries, trending and completeness of data in clinical studies.
- Generate payment request for site and vendors per the contract language, manage quarterly accruals, study budget and payment tracking systems.
- Assist with the continued development of Clinical Department including writing SOP's, guidance documents, work instructions and other procedures as needed.

Requirements:

- At least 2 years experience in Medical Device clinical research studies.
- BS preferred in Life Sciences or other technical discipline.
- Ability to perform travel an average of 10%, depending on project needs
- Demonstrated ability to juggle multiple demands, and with a high attention to detail
- Demonstrated ability to work effectively in a team environment
- Works independently with minimal supervision to meet project goals with good communication skills.

- Working knowledge of the US and International medical device regulations.
- Proven organizational abilities, and excellent written and oral communication skills.
- Exercise good independent judgment.
- Utilize strategies that address both short-term requirements and long-term Company needs.

Preferred:

- Located in Minneapolis, MN
- Experience with Neurovascular device trials